Supplementary Digital Content 2. Summary of Overall Adverse Events during the Blinded Phase

Blinded Phase Adverse Event Parameter	Enrollment through Implant until Randomization (N = 171)	Randomization Through Blinded Dosing (N = 170)	Overall Total (N = 171)
n (%) of subjects experiencing AEs*			
Subjects with at least 1 AE	125 (73.1)	145 (85.3)	162 (94.7)
Subjects with at least 1 SAE	14 (8.2)	10 (5.9)	22 (12.9)
Subjects with at least 1 AE leading to death	0 (0.0)	0 (0.0)	0 (0.0)
Subjects with at least 1 AE leading to discontinuation	Not applicable†	3 (1.8)	3 (1.8)
Subjects with at least 1 AE with at least possible relationship to study drug	Not applicable‡	71 (41.8)	71 (41.5)
Subjects with at least 1 AE with at least possible relationship to device	57 (33.3)	30 (17.6)	77 (45.0)

* A subject may belong to more than one category. † Not shown are 83 subjects that discontinued prior to randomization and receiving study drug. ‡ Not applicable since subjects had not received study drug.

AE = adverse events; n = number of subjects per category; N = total number of subjects; SAE = serious adverse events.